

3TC(TM) Tablets

lamivudine

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start 3TC Tablets.

This leaflet answers some common questions about 3TC tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist (also known as a chemist).

All medicines have benefits and risks. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the risks of you taking 3TC against the expected benefits it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the tablets.

You may need to read it again.

What 3TC tablets are used for

3TC tablets contain lamivudine which belongs to a group of medicines called antivirals.

3TC is used together with other antivirals to slow down the progression of human immunodeficiency virus (HIV) infection, which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (eg AIDS-related Complex or ARC).

3TC does not cure AIDS or kill the HIV virus, but prevents further

damage to the immune system by stopping production of new viruses.

3TC does not reduce the risk of passing the infection to others. You will still be able to pass on the HIV virus by sexual activity or by contamination with infected blood. You should still use proper precautions.

While taking 3TC and/or any other therapy for HIV disease, you may continue to develop other infections and other complications of HIV infection. You should keep in regular contact with the doctor who is looking after you.

3TC tablets are not addictive.

Your doctor may have prescribed 3TC tablets for another reason.

Ask your doctor if you have any questions about why 3TC tablets have been prescribed for you.

Before you take 3TC tablets

When you must not take them

- * **Do not take 3TC tablets if you have ever had an allergic reaction to lamivudine or any of the ingredients listed at the end of this leaflet.**

Read the Side Effects section to find out symptoms of allergy.

- * **Do not take 3TC tablets if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you**

should.

Your doctor will discuss the risks and benefits of using 3TC tablets if you are pregnant or breastfeeding.

- * **Do not use 3TC tablets to treat any other conditions unless your doctor says that you should do so.**
- * **Do not give 3TC tablets to anyone else, even though their symptoms may sound similar to yours.**
- * **Do not take 3TC tablets after the expiry or "use by" date (EXP) printed on the pack.**

If you take it after the expiry date has passed, it may not work as well.

- * **Do not take 3TC tablets if the packaging is torn or shows signs of tampering.**

If you're not sure whether you should be taking 3TC tablets, talk to your doctor.

Before you start to take them

You must tell your doctor if:

- * you are allergic to foods, dyes, preservatives or any other medicines.
- * you have, or have ever had, liver problems, for example jaundice, hepatitis, virus affecting the liver, enlarged liver or liver scarring (cirrhosis) or if you have any risk factors for liver problems, e.g. excessive alcohol intake, illegal intravenous drug use with shared equipment, iron or copper storage disorders

- * you have, or have ever had, kidney problems.
- * you have, or have ever had, problems with your pancreas.
- * you have diabetes.
- * you have any other illness, including those that you think are not related to HIV infection.

When you stop taking 3TC Tablets

If you have a long-standing viral infection of your liver (hepatitis B) it may flare up. This can cause serious illness particularly if your liver is already not working very well. If you have both HIV and hepatitis B, when you stop taking your 3TC tablets, your doctor is likely to arrange tests from time to time to check how well your liver is working and to measure virus levels.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking 3TC tablets with other medicines.

How to take 3TC tablets

Your doctor will tell you how many 3TC tablets to take and how often to take them. You will also find this information on the label of your medicine.

Do not take extra tablets. Do not take the tablets more often than you have been told.

How much to take

Adults and adolescents 12 years and older the usual dose is one 150 mg tablet twice a day or 300mg once a day. Your doctor may prescribe a different dosage.

For younger children between 3 months to 12 years of age the dose of 3TC will depend on their weight in kilograms (kg). If you are giving 3TC tablets to a child, follow your doctor's instructions. 3TC oral solution is also available for younger patients, or those who cannot swallow tablets.

How to take them

3TC tablets should be swallowed whole with a glass of water.

How long to take them

Because your medicine helps to control your condition, but does not cure it, you will need to take the tablets every day. Do not stop taking your medicine without first talking to your doctor.

If you forget to take them

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126), or in New Zealand the Poisons Centre number is 0800 POISON or 0800 764 766, or go to accident and emergency at your nearest hospital, if you think you or anyone else may have taken too many 3TC tablets. Do this even if there are no signs of discomfort or

poisoning. This may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking 3TC tablets

Things you must do

Tell your doctor or pharmacist that you are taking 3TC tablets if you are about to be started on any other medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop taking 3TC tablets, or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use 3TC tablets to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how 3TC tablets affect you.

Side-Effects

Check with your doctor as soon as possible if you have any problems while taking 3TC tablets, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, 3TC tablets can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- * **Headache.**
- * **Diarrhoea.**
- * **Fatigue/tiredness.**
- * **Abdominal discomfort and pain.**
- * **Rash.**
- * **Fever.**
- * **Unusual feelings in any part of the body, such as numbness, burning, tingling or pins and needles.**
- * **Increased bruising or bleeding.**

Changes in fat distribution have been reported in association with combination antiretroviral therapy. These may include:

- * Loss of body fat from areas such as legs, arms and face
- * Increased fat appearing in areas such as abdomen (belly) and other internal organs, breasts and the back of the neck

Within the first few weeks of treatment with anti-HIV medicines, some people, particularly those that have been HIV positive for some time, may develop inflammatory reactions (eg pain, redness, swelling, high temperature) which may resemble an infection and may be severe. It is thought that these reactions are caused by a recovery in the body's ability to fight infections, previously suppressed by HIV. If you become concerned about any new symptoms, or any changes in your health after starting HIV

treatment, please discuss with your doctor immediately.

Ask your doctor or pharmacist to answer any questions you may have.

Some people are allergic to medicines.

If you have any of the following symptoms soon after starting to take your medicine, DO NOT TAKE ANY MORE 3TC TABLETS and tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- * Skin troubles such as lumpy skin rash or "hives".
- * Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.
- * Wheezing, chest pain or tightness.
- * Fainting.

These are very serious side effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation. All these side effects are very rare.

If you have any of the following symptoms soon after starting to take your medicine, DO NOT TAKE ANY MORE 3TC TABLETS and tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- * **Severe stomach pain or cramps.**
- * **Nausea.**
- * **Vomiting.**

These side effects may be due to a condition called pancreatitis.

If you are on medication for HIV and become very sick, with fast breathing, stop taking 3TC tablets and consult your doctor immediately. You may have a condition known as "lactic acidosis". The fast breathing is due to high acid levels in the blood. Your liver may not be working properly and gets big and fatty.

This can be life threatening. This illness occurs more often in women than men.

See your doctor if you feel generally unwell with loss of appetite, nausea, vomiting, itching, yellowness of the skin or eyes or dark coloured urine, or if the blood tests of your liver function are abnormal. It is likely you will have to stop taking 3TC tablets.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Some people may get other side effects while taking 3TC tablets. If you are concerned, talk to your doctor or pharmacist.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After taking 3TC tablets

Storage

Keep the tablets where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

Keep 3TC tablets in a cool, dry place where it stays below 30 degrees C.

Do not store the tablets, or any other medicine, in a bathroom or near a sink.

Do not leave them in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep your 3TC tablets in the bottle with the cap tightly closed until you take them.

If you take 3TC tablets out of their pack they may not keep well.

Disposal

If your doctor tells you to stop taking 3TC tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What 3TC tablets look like.

3TC 150 mg Tablets are white, film-coated, modified diamond shaped tablets engraved "GX CJ7" on one face.

3TC 300 mg Tablets are grey, film-coated, modified diamond shaped tablets engraved "GX EJ7" on one face.

3TC tablets are supplied in a white high-density polyethylene bottle, with a plastic cap. Each bottle contains 30 (300 mg) or 60 (150 mg) tablets and is in a carton.

Ingredients

3TC tablets contain either 150mg or 300mg of lamivudine per tablet.

3TC Tablets also contain Microcrystalline cellulose (460), magnesium stearate (572), titanium dioxide (171), hypromellose (464), sodium starch glycollate, macrogol 400 and polysorbate 80 (433) and purified water. The 300 mg tablets also contain black iron oxide (E172).

Sponsor

Your 3TC tablets are supplied by:
GlaxoSmithKline Australia Pty Ltd
1061 Mountain Highway
Boronia
Victoria, 3155
Australia.

or

GlaxoSmithKline NZ Ltd
Cnr Albert & Customs Streets
Downtown Auckland
New Zealand

Further Information

This is not all the information that is available on 3TC tablets. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you the individual advice you need. You may also be able to find out more information about your disease from books, for example in public libraries.

Counselling is also available from your local AIDS council.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on
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The information provided applies only to: 3TC(TM) tablets.
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3TC 150mg tablets:

AUST R 54313

3TC 300mg tablets:

AUST R 81359

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